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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

STATE OF CALIFORNIA *ex rel.* JAYDEEN VICENTE and JAYDEEN VICENTE Individually, Relator, v. ELI LILLY AND COMPANY, Defendant.	Case No. 07-cv-04911-CRB Assigned to: Hon. Charles R. Breyer **DEFENDANT ELI LILLY AND COMPANY'S OPPOSITION TO MOTION TO REMAND** Date: December 7, 2007 Time: 10:00 a.m. Place: Courtroom 8, 19th Floor

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Defendant Eli Lilly and Company's ("Lilly") Notice of Removal set forth two separate and independent grounds for this Court's exercise of jurisdiction in this case. First, this Court has original jurisdiction under 28 U.S.C. § 1331 because Relator expressly alleges violations of, and "liability under," the federal False Claims Act, 31 U.S.C § 3729. *See* Compl. ¶¶ 64, 210-211 & p. 43; *Barraclough v. ADP Automotive Claims Services, Inc.*, 818 F. Supp. 1310, 1312 (N.D. Cal. 1993) (plaintiff's allegation of a federal claim entitles defendant to a federal forum). Second, this Court also has "substantial federal question" jurisdiction because Relator's state law claims "necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005).

Relator's Motion to Remand does nothing to undermine either of these jurisdictional bases. First, with regard to her own express allegations of federal liability, Relator's explanation is limited to three sentences, which concede that the Complaint does in fact allege that Lilly's conduct is actionable under federal law but then ask this Court to ignore these allegations. (Motion at 5). Such meager efforts cannot somehow undo the Complaint's clear allegations of "liability under" federal law and conduct "punishable under" federal law." *See* Compl. at p. 43 (alleging that Lilly is liable "[u]nder the State and Federal False Claim Acts"); ¶ 210 (alleging "Lilly's liability under §§ 3729(a)(1) and (a)(2) of the Federal False Claims Act . . . "); ¶ 211 (alleging "Lilly's conduct is also punishable under § 12651(a)(3) of the Federal False Claims Act . . . "); ¶ 64 (citing federal False Claims Act).

Second, Relator's claims *require* construction and application of three areas of federal law: (1) the FDCA, 21 U.S.C. § 301, *et seq*., which regulates the marketing of prescription drugs; (2) the federal Medicare and Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320, *et seq*. ("AKS"), which prohibits certain remuneration with respect to the sale of prescription drugs; and (3) federal Medicaid law, which determines the drugs for which a state must provide coverage, *see* 42 U.S.C.

§§ 1396r-8(d)(B), (d)(4). While Relator conclusorily asserts that these issues are neither substantial nor disputed, the Complaint alleges absolutely no California law basis to support the supposed "falsity" of the claims that form the basis of this action. Absent these federal issues, therefore, the Complaint does not allege any falsity. These disputed federal issues are therefore at the core of this case and must be adjudicated.

Moreover, the adjudication of these rules requires more than merely interpreting federal definitions in the course of construing a California statute; it requires the balancing of federally encouraged and federally prohibited conduct. These issues involve an "intricate regulatory scheme including detailed federal funding provisions [that] requir[es] some degree of national uniformity in interpretation" and therefore support federal jurisdiction. *See Louisiana ex rel. Foti v. Eli Lilly and Co.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005) (denying motion to remand in nearly identical case); *West Virginia v. Eli Lilly and Company*, 476 F. Supp. 2d 230, 234 (E.D.N.Y. 2007) (same); *Mississippi ex rel. Hood v. Eli Lilly and Co.*, 2007 WL 1601482 (E.D.N.Y. June 5, 2007) (same); *see also County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1030 (N.D. Cal. 2005) (denying motion to remand in similar case raising issues under Medicaid Drug Rebate Statute).

ARGUMENT

I. FEDERAL JURISDICTION EXISTS BECAUSE RELATOR ALLEGES LIABILITY UNDER THE FEDERAL FALSE CLAIMS ACT

Relator's assertion of a federal claim, standing alone, entitles Lilly to a federal forum, *Barraclough*, 818 F. Supp. at 1312, and distinguishes this case from any Zyprexa case in which remand was granted. Here, Relator has alleged liability under federal law in no less than four separate places. Paragraph 64 of Relator's Complaint alleges that Lilly has caused reimbursement claims to be submitted in violation of the Federal False Claims Act. Compl., ¶ 64 (citing federal False Claims Act). Relator then entitles an entire section of her Complaint "**Under the State and Federal False Claims Acts.**" Compl. at p. 43 (bolding original; underlining added). Finally, in the final paragraphs preceding the ostensible identification of her claims under the California False

Claims Act ("CFCA") (Counts I and II) and the California Business and Professions Code (Counts III and IV), Relator alleges "Lilly's liability under §§ 3729(a)(1) and (a)(2) of the Federal False Claims Act" and that Lilly has engaged in conduct "punishable under . . . the Federal False Claims Act") (emphasis added). Compl. ¶¶ 210-211.

Plaintiff is the master of her complaint and may avoid the exercise of federal jurisdiction by pleading only state claims which do not raise any substantial and disputed questions of federal law. *See Opulent Funds, L.P v. NASDAQ*, 2007 WL 3010573, *2 (N.D. Cal. Oct. 12, 2007). In this case, rather than evading the exercise of federal jurisdiction by pleading only state law claims, Relator has expressly invoked federal jurisdiction by alleging liability under federal law.

While it is true that merely incidental references to federal law are not enough to create federal jurisdiction, it is likewise true that a complaint that goes beyond an incidental reference and actually asserts federal liability does present a federal question. *Longoria v. Clarke*, 2007 WL 1960614, *3 (W.D. Wa. July 2, 2007). In *Longoria*, the Complaint alleged that defendants had violated plaintiffs' rights under state and federal law but did not list any federal causes of action. *Id*. After defendants removed the action, plaintiffs moved to remand, claiming that their reference to federal law should be ignored. *Id*. at *2. The court properly rejected this argument, finding that "even though plaintiffs did not plead violations of federal law in the Causes of Action section of the original complaint, the specific factual allegations sufficiently support claims under both federal and state law." *Id*. at *3.

Here, Relator does far more than incidentally reference federal law.[1] Rather, the Complaint specifically asserts Lilly's alleged liability under federal law by alleging necessary elements to make out a claim under the federal False Claims Act. *See, e.g*, Compl. ¶¶ 29-31 (alleging that the federal government funds part of the State of California's Medicaid reimbursement

[1] The sheer number of Relator's other citations to federal law and regulations support the conclusion that the substantive references to federal law on page 43, ¶ 210 (p. 44), ¶ 211 (p. 44), and ¶ 64 are by no means incidental. *See* ¶¶ 39, 40, 41, 53, 54, 60, 70, 192, 193, 197, 198, 202 (p. 43), 204 (p. 43), 206 (p. 43) and 229 (other citations or references to federal statutes or regulations); ¶¶ 2, 4, 5, 7, 9, 10, 11, 20, 22, 45, 49, 50, 51, 52, 54, 55, 56, 59, 60, 61, 62, 63, 64, 74, 75, 80, 81, 85, 86, 87, 88, 90, 91, 96, 98, 99, 101, 102, 105, 108, 123, 142, 167, 168, 170, 173, 177, 179, 180, 181, 183, 184, 185, 216, 218, 220, and 224 (references to "off-label" or "medically indicated" uses, concepts defined solely by federal law, *see* pp. 5-7, *infra*).

program). *Longoria* makes clear that a plaintiff who has alleged federal liability cannot avoid remand by characterizing her references to federal law as "inadvertent."

Relator's only response is her assertion that the Complaint's invocation of federal law should be ignored because Relator only seeks "civil penalties" under California law. As an initial matter, just as the names given to the causes of action in *Longoria* were not dispositive, neither is the prayer for relief here. Moreover, Relator ignores that she also seeks restitution of the amounts Lilly has allegedly been unjustly enriched by the sale and prescription of Zyprexa in California and other states and a catch-all seeking *any* appropriate relief under federal law. Compl. ¶¶ 240, 250, and p. 52. Because Relator's Complaint expressly invokes and asserts liability under federal law, this Court has jurisdiction over this action.

II. FEDERAL JURISDICTION EXISTS FOR THE SEPARATE AND INDEPENDENT REASON THAT RELATOR'S STATE LAW CLAIMS RAISE SUBSTANTIAL, DISPUTED QUESTIONS OF FEDERAL LAW

As set forth in Lilly's Notice of Removal, separate and independent from the jurisdiction based on Relator's express invocation of federal law, this Court has "substantial federal question" jurisdiction under the principles set forth in *Grable*. Relator attempts to respond to this argument by assuring this Court that her claims only raise issues of state law that happen to incorporate federal definitions, and that the real issues in this case will involve California law. For instance, Relator contends that "the question is not whether Lilly caused submissions of a claims [sic] for off-label use, as defined by federal law, but rather whether Lilly caused the submission of a false or fraudulent claim, as defined by California law." (Motion at 6). Remarkably, however, Relator does not cite to any provisions of California law actually relevant to her allegations. Indeed, finding no relevant California law, Relator devotes paragraphs to Florida law, (Compl. ¶¶ 40-41) which, as used in this instance, obviously has no application here. The other 250 paragraphs of the Complaint focus entirely on federal law regarding "off-label" marketing and reimbursement.

The Relator cites to nothing in California law that would render "false" a claim for Medicaid reimbursement that was the result of off-label marketing or a physician kickback. Rather, these concepts – which are at the core of Relator's allegations of "falsity" – are entirely creations of federal law which establishes the rules governing Medicaid reimbursement. More specifically, these

concepts do not simply involve federal definitions; they are part of the federal regulatory scheme delimiting how federal dollars may be used to fund state Medicaid programs and, as described below, involve complex balancing of a multitude of federal interests. *See West Virginia*, 476 F. Supp. 2d 230, 233 ("state's obligation to reimburse for Zyprexa, using largely federal funds presents a substantial and disputed federal issue under *Grable*."); *County of Santa Clara*, 401 F. Supp. 2d at 1028-29 (finding a substantial and disputed federal question regarding the complex regulatory scheme of Medicaid reimbursement); *Municipality of San Juan v. Corporation Para El Fomento Economico De La Ciudad Capital*, 415 F.3d 145, 148 (1st Cir. 2005) (finding federal jurisdiction under *Grable* supported, in part, by fact that "the funds at issue are federal monies").[2]

In short, Relator's claim that this case turns on California law is belied by the fact that she is unable to cite any such provision of California law. This is not a case, therefore, where a plaintiff's state-law claims simply incorporate a federal standard. Instead, this is a case in which Relator's entire theory of the case requires the application of a complex body of federal law and implicates a federal regulatory scheme governing the allocation of federal funds. As described below, these questions are both disputed and substantial.

A. The Complaint Raises Substantial and Disputed Federal Issues Requiring Interpretation of the FDCA

Relator also alleges that Lilly caused "false" claims to be submitted by "illegally" promoting Zyprexa for "off-label" use. Compl. ¶ 62. As Relator herself concedes, "illegally" in this allegation means "illegal" under federal law. *See* Compl. ¶¶52 ("Lilly's conduct also materially and wantonly violated the FDA's regulations and federal law governing off-label marketing and truthful labeling and promotion of prescription drugs."); p. 11 ("**FDA Regulation of Drug Companies and their Marketing Practices**") (emphasis original); p. 13 ("***Federal Law Prohibits Off-Label Marketing*** . . .") (emphasis original); ¶ 59 ("Off-label marketing by pharmaceutical companies is

[2] Relator's Complaint attempts to avoid the indisputable fact that millions of dollars of federal funds are at issue by contending that the *West Virginia* case is somehow different than this one because the federal government funded 72.82% of the State of West Virginia's Medicaid costs but only 50% of the State of California's Medicaid costs. (Motion at 12); Federal Financial Participation in State Assistance Expenditures FY 2007, 70 Fed. Reg. 229 (Nov. 30, 2005). This is a distinction without a difference. Moreover, Relator's suggestion that federal courts may hear the West Virginia case but not this one, despite the fact that the cases raise identical issues, is simply untenable.

closely regulated by the FDA . . .") (emphasis added).[3]

The FDA has plenary and exclusive responsibility to regulate prescription medicines sold in the United States and to enforce laws with respect to such medicines. 21 U.S.C. § 301, *et seq*. (cited in Compl. at ¶ 54). In accordance with this responsibility, the FDA has implemented an intricate regime of regulations related to promotion of prescription medicines. *See* 21 U.S.C. § 393(b)(1) and (2)(B) (providing that the FDA shall ensure that "drugs are safe and effective" by "promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products.") These regulations are anything but simple.

Thus, Relator suggests that federal law bars all off-label marketing and that Lilly therefore violated federal law by allegedly promoting Zyprexa for off-label uses. Compl. ¶¶ 59-64. Contrary to Relator's claim, however, the Federal Food, Drug, and Cosmetic Act does not expressly bar off-label promotion or marketing, and the FDA has established a complex set of regulations on these issues. The FDA, for example, expressly permits the dissemination of certain information regarding investigational uses of approved new drugs. *See* 21 C.F.R. 312.7(a); *see also* 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994) ("The agency has recognized the need among health care professionals for peer review and dissemination of the latest significant scientific data and information on drugs and devices in scientific journals.") Similarly, the FDA authorizes manufacturers to respond to unsolicited requests for information concerning unapproved uses. 21 U.S.C. § 360aaa-6(a); 21 C.F.R. 99.1(b). These rules recognize that scientific information concerning unapproved uses is essential to the proper practice of medicine over which the FDA has no jurisdiction and which – as the FDA itself has recognized – may require prescribing for off-label uses. *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001); 21 U.S.C. § 396. The line between prohibited off-label marketing and dissemination of appropriate and necessary scientific information regarding prescription medicines is therefore an issue that raises a substantial federal

[3] Relator devotes considerable energy to arguing that "Lilly's anticipated affirmative defenses, including federal question defenses such as preemption, do not confer subject matter jurisdiction." (Motion at 5). This is a straw man—in these motions, Lilly has not raised any preemption argument and does not assert that any of its defenses create federal jurisdiction. Instead, Lilly contends that federal jurisdiction lies because: (1) Relator has expressly invoked federal law and (2) alleged claims that raise substantial and disputed issues of federal law.

question. *See West Virginia*, 476 F. Supp. 2d at 233 (finding that false claims act cause of action regarding state's participation in the federal Medicaid program raises a substantial and disputed federal issue under *Grable*). There are, in addition, Constitutional limits to the application of FDA regulations regarding communication to physicians. *See Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), vacated on other grounds, *Washington Legal Found. v. Henney*, 128 F. Supp. 2d 11 (D.D.C. 2000)

This issue is also disputed. Relator alleges that the marketing materials attached to the Complaint violated the alleged federal prohibition on off-label marketing. Compl. ¶¶ 59-64. Lilly disputes Relator's apparent suggestion that any reference to an off-label use of an approved drug runs afoul of federal law. Rather, Lilly will contend that the various marketing materials attached to the complaint were appropriate under federal law. The appropriateness of those materials under federal law is therefore a disputed issue in this litigation.

In short, there is no way to resolve Relator's allegation that Lilly's promotional practices caused the submission of "false" claims without analyzing the Federal Food Drug and Cosmetic Act and the FDA's regulations in determining whether the particular allegations set forth in the Complaint constitute a violation of federal law. Relator has not alleged any provision of state law that is any way relevant to this determination. Therefore, it is clear that federal law is at the core of Relator's CFCA claims and that these claims raise "an actually disputed and substantial" federal issue under *Grable*.

B. The Complaint Raises Substantial and Disputed Federal Issues Regarding Whether Certain Payments Violate the Federal Anti-Kickback Statute

The second substantial and disputed federal issue raised by the Complaint is whether Lilly's alleged payment of honoraria and speakers fees to physicians violated the federal anti-kickback statute ("AKS"). Compl. ¶ 152. For example, while Relator alleges at paragraph 198 of the Complaint that Lilly allegedly paid kick-backs in the form of "speaker fees,' honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa," Relator elsewhere acknowledges, (Compl. ¶ 200, p. 40), as she must, that not every payment made to a physician violates the federal AKS. To the contrary, the federal AKS only

prohibits payments knowingly and willfully meant to "induce" the recipient (1) to refer an individual to a person for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (2) to purchase or lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal Health care program. Compl. ¶ 192 (quoting 42 U.S.C. § 1320a-7b(b)(2)(A) & (B)). Furthermore, there are more than 20 statutory exceptions and regulatory safe harbors under the federal AKS that expressly protect certain payments, including payments provided by pharmaceutical manufacturers to both physician and non-physician service providers, that comply with the safe harbor requirements. Indeed, depending on the circumstances of the payments and the services provided, the personal services safe harbor, 42 C.F.R. § 1001.952(d), may in fact allow as a matter of law many of the payments Relator alleges were improper. Interpretation of the federal AKS constitutes a substantial federal question.[4]

This substantial federal question is disputed in this case. Although Relator concludes that such remuneration was, in fact, paid, thereby resulting in false claims being filed with the government, Relator admits in the allegations that the stated purposes of those payments were legitimate, including speaker fees, honoraria, and educational grants. Compl. ¶ 198 (p. 40, 42) (alleging that "Lilly paid, and physicians accepted, unlawful remuneration, including cash payments thinly-veiled as 'speaker fees,' honoraria, and . . . educational grants"). In each instance, Lilly contends that its payments to physicians were entirely proper under the federal regime. In each instance, the Court must examine the individual circumstances of the payment and services provided to determine whether the AKS applies and, if so, whether any of the safe harbors protects the challenged conduct. As with Relator's "marketing" allegations, it is therefore simply not possible to resolve Relator's "kickback" allegations without relying on federal law, and there is no California

[4] Though Relator also cites California's Health & Safety Code §§ 119400-02, these statutes do not provide an alternative and independent state law basis for imposing False Claims Act liability. Indeed, Relator never cites any particular provision of California's Health & Safety Code §§ 119400-02 which Lilly has allegedly violated. The reason Relator does not do so is because she cannot: these California statutes merely require that manufacturers establish compliance programs regarding contributions to physicians (which programs must accord with the *federal* Officer of Inspector General's guidelines) and do not impose any substantive limits on remuneration to health care providers. Relator's claim that Lilly somehow violated California's Health & Safety Code is therefore without merit.

law that bears on the issue.

C. The Complaint Raises Substantial and Disputed Federal Issues Regarding Whether Federal Law Requires that California Provide Coverage For Certain "Off-Label" Uses of Zyprexa

Even if Relator could support her theories that Lilly violated the rules governing the "marketing" of drugs and the rules governing the payment of "kickbacks," in order to prevail on her CFCA claim, she must she must also independently prove that federal law would have permitted the State to refuse to provide coverage for the "off-label" usages of Zyprexa at issue as well as usages resulting from the alleged violations of the federal AKS.

Relator does not, and cannot, dispute that every step the state of California takes with regard to Medicaid coverage of an FDA-approved drug is subject to strict federal mandates. *See* Compl. ¶ 37 ("Federal statutes and regulations restrict the drugs and drug uses that the federal and state governments will pay for Medicaid programs.") *See also West Virginia*, 476 F. Supp. 2d at 233 ("The parameters and requirements of [West Virginia's participation in the federal Medicaid Program] are governed by federal law.") Specifically, as set forth in more detail in the Notice of Removal, ¶¶ 32-36, if a state elects to provide coverage for prescription drugs, it must comply with the federal requirements set forth in 42 U.S.C. § 1396r-8, the Medicaid Drug Rebate Statute. *See* 42 U.S.C. § 1396b(i)(10)(A). If a state does not comply with these federal requirements, it is not entitled to federal funding of its Medicaid program (and, as noted earlier, the federal government provides 50% of the State of California's Medicaid funding). One of these requirements is that a state must provide coverage for "a covered outpatient drug," 42 U.S.C. § 1396r-8(d), defined in the Medicaid Drug Rebate Statute as a drug that is "approved for safety and effectiveness as a prescription drug" by the FDA and that is prescribed for outpatient use (subject to some exceptions) for a "medically accepted indication."[5] A "medically accepted indication" means any use for a covered outpatient drug that is approved under the federal FDCA, or the use of which is supported

[5] The Medicaid Drug Rebate Statute does permit states to impose certain limited exclusions and restrictions on coverage for "covered outpatient drugs." *See* 42 U.S.C. § 1396r-8(d). The Complaint does not, however, allege that any such provisions of state law are relevant to Relator's claims. While the Complaint does inexplicably make reference to certain provisions of Florida law (Compl., ¶¶ 40-41), these references appear to be the result of cutting-and-pasting from the pleadings in another action.

by one or more citations included or approved in any one of the compendia described in" the federal Medicaid Rebate Statute. *See* 42 U.S.C. § 1396r-8(k)(6); *see also* Complaint ¶ 39 (citing 42 U.S.C. § 1396r-8(k)(3) and (6) and discussing compendia).

Putting these several provisions together, federal law dictates that the State must provide coverage for usages of Zyprexa which are specifically approved under the federal FDCA or listed in the relevant compendia. Here, Relator and Lilly disagree on the interpretation of these federal authorities. Relator contends that federal law supports use of Zyprexa in adult schizophrenic or bipolar patients only, Compl. ¶ 70, and does not therefore require states to provide reimbursement for other usages. Compl. ¶¶ 180-181. Lilly disputes these claims, contending that federal authority supports use of Zyprexa to treat a broader range of disorders, including all of those listed in the various compendia, *Motion to Dismiss* (Doc. No. 8) at 19, and that federal law therefore requires California to provide coverage for such usage. *Id*. at 18-19; *see also U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127, *2 (E.D. Mo., April 21, 2006) (unpublished) ("covered outpatient drugs" subject to reimbursement under federal law).

Because federal law controls the core question of whether the State was obligated to provide coverage for the prescription of Zyprexa to treat illnesses other than schizophrenia and bipolar disorder and because Lilly and Relator assert competing interpretations of this law, it is clear that the Complaint raises a "substantial and disputed" question under *Grable*. Indeed, Relator does not allege any state law basis that would allow the State to deny reimbursement for the at-issue usages of Zyprexa. Simply put, Relator's central claim—the allegation that Lilly encouraged physicians to submit unreimbursable claims to the State for reimbursement—depends on federal law and involves federal funds, and should be resolved by the federal courts.

D. Federal Jurisdiction Over This Case Will Not Upset the Balance of Federal and State Judicial Responsibilities

Under *Grable*, if a case presents substantial and disputed federal questions and assertion of federal jurisdiction over the case "would not materially affect, or threaten to affect, the normal currents of litigation" or cause other threatening structural consequences, then "there is no good reason to shirk from federal jurisdiction. . . ." *Grable*, 545 U.S. at 319-20. Here, as in the

indistinguishable cases from Louisiana, West Virginia, and Mississippi, the exercise of federal jurisdiction is "consistent with congressional judgment about the sound division of labor between state and federal courts," *West Virginia*, 476 F. Supp. 2d at 234, citing *Grable*, 545 U.S. at 313-14, and would further the uniform interpretation of an "intricate federal regulatory scheme." *West Virginia*, 476 F. Supp. 2d at 239.

The exercise of federal jurisdiction here would not upset the federal/state balance by causing a significant rise in the caseload of federal courts. First, the federal judiciary has already chosen to exercise jurisdiction over Zyprexa cases such as this one, by denying motions to remand in virtually identical cases and establishing a Zyprexa MDL to hear this type of case. *See County of Santa Clara.*, 401 F. Supp. 2d at 1031 (finding that exercise of jurisdiction by federal courts over similar cases undermined plaintiff's argument that the federal-state balance would be disrupted); *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 457 F. Supp. 2d 77, 81 (D. Mass. 2006) (noting that pendency of MDL involving similar cases indicated that acceptance of federal jurisdiction would not upset balance of federal and state judicial responsibilities). Second, given that false claims act cases must be brought by or on behalf of states, the number of potential cases is necessarily finite. There is simply no basis to claim that the exercise of federal jurisdiction here would significantly increase the caseload of the federal court.

Relator's only argument to the contrary is that the lack of a private right of action to recover reimbursement for Medicaid payments indicates a Congressional intention not to allow for federal jurisdiction. (Motion at 8). This argument is without merit. The Supreme Court made clear in *Grable* that a specific federal right of action is not required for a finding of federal jurisdiction. *See Grable*, 545 U.S. at 318; *County of Santa Clara*, 401 F. Supp. 2d at 1030 (rejecting plaintiff's contention that Congress' failure to create a federal cause of action barred the exercise of federal jurisdiction).

Moreover, contrary to Relator's suggestion, Lilly does not contend that *all* state actions to recover Medicaid funds from a third party raise substantial federal questions. Rather, consistent with *Grable*, the issue here is not whether there is federal jurisdiction over state Medicaid suits generally, but whether the particular set of facts and issues in *this* case raises a substantial

federal question that gives rise to federal jurisdiction in *this* case.

III. THIS COURT SHOULD FOLLOW THE DECISIONS FINDING THAT LIKE FALSE CLAIMS ACT ALLEGATIONS RAISE SUBSTANTIAL AND DISPUTED QUESTIONS UNDER FEDERAL MEDICAID LAW

Three directly on-point decisions from the Zyprexa MDL confirm that federal jurisdiction is proper here. *See Mississippi ex rel. Hood v. Eli Lilly and Co.*, 2007 WL 1601482 (E.D.N.Y. June 5, 2007); *West Virginia ex rel. McGraw v. Eli Lilly and Co.*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007); *Louisiana ex rel. Foti v. Eli Lilly and Co.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005). In each of these cases, the states sought to recover costs allegedly incurred by their Medicaid programs as a result of Lilly's allegedly wrongful promotion of Zyprexa and the alleged concealment of its side effects. And in each case, the federal court held that federal question jurisdiction existed under *Grable*. As Judge Weinstein explained in *West Virginia*, "the question of the state's obligation to reimburse its insureds for Zyprexa, using funds largely provided by the federal government, is essential to the state's theory of damages and presents a substantial and disputed federal issue under *Grable*." *West Virginia*, 476 F. Supp. 2d at 233. These decisions are indistinguishable from this case and they should control the Court's analysis here.

These decisions find further support in other Medicaid reimbursement cases, including this Court's decision in *County of Santa Clara*. In that case, plaintiff asserted a violation of the CFCA based on alleged misrepresentation of prescription drug prices under the Medicaid program. Judge Alsup found that plaintiff's CFCA claim required the application of the Medicaid Rebate Statute because plaintiff's theory of falsity turned on the price limits set forth in that statute. 401 F. Supp. 2d at 1026-27; *see also AWP Litigation*, 457 F. Supp. 2d at 80 (finding "that the meaning of AWP in the federal Medicare statute is a substantial federal issue that properly belongs in federal court.") The Court also concluded that the federal issues were "substantial" because they "could heal or injure the complex regulatory scheme of distributing outpatient medications" and "disputed" because defendants the parties disagreed regarding the interpretation of the relevant federal law. 401 F. Supp. 2d at 1027, 1028. Finally, the Court rejected plaintiff's claim that exercising jurisdiction would disrupt the federal-state balance. In making this finding, the court noted that federal courts had exercised jurisdiction over similar cases and rejected plaintiff's

contention that the lack of a federal cause of action barred removal. *Id*. at 1029, 1030. This Court's reasoning in *County of Santa Clara* should be applied here.

Rather than distinguish these cases, Relator rests her remand argument on the claim that this Court should ignore the Zyprexa MDL court's decision in favor of remand decisions in four allegedly similar cases. *Alaska v. Eli Lilly and Co.*, 2006 WL 2168831 (D. Ak. July 28, 2006); *Pennsylvania v. Eli Lilly and Co.*, 2007 WL 1876531 (E.D. Pa. June 27, 2007);[6] *South Carolina ex. rel. McMaster v. Eli Lilly & Co.*, 2007 WL 226193 (D. S.C. Aug. 3, 2007); *Utah v. Eli Lilly & Co.*, 2007 WL 2482397 (D. Utah Sept. 4, 2007).[7] As indicated above, however, these decisions are distinguishable for at least two independent reasons. First, unlike this case, none of the plaintiffs in the remanded actions had asserted an express claim for violation of the federal False Claims Act. *See* Compl. ¶¶ 64, 210-211 & p. 43. Relator's assertion of such a claim here provides Lilly with a right to a federal forum. *Barraclough*, 818 F. Supp. at 1312.

Second, in each of the remanded cases, plaintiffs framed their claims as arising primarily under state law. In *Utah*, for instance, the District Court expressly noted that the Complaint's reliance on the state-law definition of the term "medically necessary" provided a separate and independent state-law basis for plaintiff's false claims act cause of action. *See*, *e.g.*, *Utah*, 2007 WL 2482397 at *4. The court therefore concluded that "[g]iven these multiple bases, resolution of [the state false claims act cause of action] does not hinge solely on a federal question." *Utah*, 2007 WL 2482397 at *4. Similarly, the *Pennsylvania* court concluded that the particular Pennsylvania state-law claims asserted were "fact-bound," "situation-specific," and did "not turn on the interpretation of federal law" or even "require the construction or interpretation of a disputed

[6] The United States District Court for the Eastern District of Pennsylvania issued essentially the same decision in *Pennsylvania Employees Benefit Trust Fund v. Eli Lilly & Co., Inc.*, 2007 WL 2916195 (E.D. Pa. Oct. 5, 2007). This case is distinguishable on the same grounds as it is distinguishable from the earlier Pennsylvania decision, as set forth in more detail above. It is also distinguishable because, like *Alaska*, the complaint did not involve any allegations of Medicaid fraud.

[7] Relator contends that these cases evidence "a split of authority" on the issue of federal question jurisdiction dictating that remand is required. (Motion at 7). Contrary to this claim, no such hard and fast rule exists, as evidenced by decisions in which courts have noted splits of authority but denied motions to remand. *See, e.g., Chapman v. 8th Judicial Juvenile Probation Bd.*, 22 F. Supp. 2d 583, 584-86 (E.D. Tex. 1998); *Roseman v. Best Buy Co., Inc.*, 140 F. Supp. 2d 1332, 1333 (S.D. Ga. 2001).

issue of federal law." *Id*., at *5, *6.[8]

The types of claims at issue in the remanded cases also demonstrate the state-law emphasis of those case. In *Alaska*, for instance, the complaint did not include a Medicaid false claims count but, rather, asserted state-law claims for strict products liability, fraud and negligent misrepresentation (based on an alleged failure to warn), negligence, and unfair trade practices. *See Alaska*, 2006 WL 2168831 at *1. Similarly, the *Pennsylvania*, *South Carolina and Utah* plaintiffs chose to assert state-law causes of action such as failure to warn, negligence, breach of warranty, fraud, and misrepresentation based on alleged physical injuries caused by Zyprexa. *See Pennsylvania*, 2007 WL 1876531 at *1; *South Carolina*, 2007 WL 226193 at *1; *Utah*, 2007 WL 2482397 at *1.

In short, unlike in the cases in which remand has been granted, Relator has alleged absolutely no California-state law basis as a predicate to support the allegations of "falsity" that form the purported basis for this action. *Compare Utah*, 2007 WL 2482397 at *4 (setting forth independent state law basis for false claims act allegation). The CFCA requires not just the submission of a claim but the submission of a "false" claim. Relator must therefore point to some body of law suggesting that the claims at issue are "false." Here, Relator has pointed this Court only to federal law. This fact, together with Relator's express allegations of liability under federal law, make this case distinguishable from the cases cited by Relator and render the exercise of federal jurisdiction proper.

[8] Relator quotes language from the *Pennsylvania* decision to suggest that Relator's claims here are "fact-specific and based on state law." (Motion at 8). This claim is remarkable because Relator's Motion to Remand does not set forth any such facts.

CONCLUSION

For all the foregoing reasons, Defendant Eli Lilly and Company respectfully requests that the Court deny Relator's Motion to Remand.

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